# ATSDR Position Paper
# The Role Of Cleavage Fragments In Asbestiform Fiber Analysis

## Introduction

In this paper, the Agency for Toxic Substances and Disease Registry (ATSDR) presents its position on how cleavage fragments—pieces broken off from nonfibrous serpentine and amphibole materials—should be treated for health assessment purposes as compared to asbestos fibers. ATSDR has concluded that in analyzing air sampling results, all particles meeting dimensional and mineralogical definitions of asbestos fibers, whether arising from cleavage or from crystalline fiber growth, contribute to risk and should be counted as fibers. ATSDR supports the recent air sampling analysis performed by the U.S. Environmental Protection Agency (EPA) in El Dorado Hills, California. The Agency does not agree with the recent critique of the EPA analysis published by the R.J. Lee Group [1].

## Background

Asbestos is a silicate mineral proven to cause lung disease. Increasing knowledge of its toxicity has resulted in its diminishing industrial importance. Releases occur today from former commercial materials and from intentional or unintentional disruption of natural asbestos deposits. Asbestos inhaled into the lung may remain and eventually cause asbestosis, pleural disease, lung cancer, or mesothelioma. Exact disease mechanisms are still under investigation. Two distinct properties of asbestos fibers are the main contributors to toxicity:

1. **Dimensions (length and width) of fibers.** Long particles cannot be removed by macrophages and elicit an inflammatory response in the lung. Thinner particles penetrate the lung tissues and are translocated to mesothelial tissues surrounding the lung and cause cellular changes potentially leading to mesothelioma. Fiber width also influences how deeply a fiber reaches into the lung and whether it escapes upper respiratory clearance mechanisms.

2. **Durability of the mineral particle in the lung.** Durability is a function of the chemical and crystallographic makeup of the fiber. Long latency periods (times from exposure to disease) are required for most asbestos-related diseases, so fibers that remain unchanged in the lungs for years contribute more risk of disease. Amphibole asbestos fibers are more durable than chrysotile (serpentine) and thus have greater toxicity.

Mineral deposits where asbestos is found contain a continuum of material, ranging from commercial grade asbestos (long, flexible, weavable fibers) to very short choppy particles that may not even fit the definition of a fiber (length to width ratio 3:1 or greater). Most fibers arise from crystalline growth or physical processes that break off of solid mineral along cleavage planes. *Cleavage fragments* are generally defined as particles and fibers that form when nonfibrous forms of amphibole and serpentine minerals split (as opposed to crystalline fiber growth) [2]. Cleavage fragments can have the same dimensions and aerodynamic properties as fibers. Cleavage fragments have identical chemical formulas as fibers from same mineral, but may differ from fibers in surface chemistry and flexibility. The central issue of the cleavage

fragment controversy lies in how potential differences between cleavage fragments and fibers (from crystalline growth) affect the potency of these particles to induce lung cancer or mesothelioma.

**Findings**

ATSDR's position, that particles meeting dimensional and mineral class definitions of asbestos fibers must be counted, is based upon four facts:

- **No protocols.** No accepted federal, international, or other protocols are available to allow for accurate classification of individual particles as cleavage fragments or fibers. Analytical differentiation of cleavage fragments from asbestiform particles in air samples is strictly subjective.
- **Analogies to similar fibers.** Size and durability are critical toxicity factors. Durable fibers of the correct size cause disease similar to asbestiform asbestos.
- **Epidemiologic evidence.** Limited epidemiology data suggest that cleavage fragments may play a role in disease.
- **Lack of toxicity data.** No adequate animal and human studies of cleavage fragments are available to demonstrate that these fragments are without disease risk.

The following sections discuss these four facts.

***No accepted analytical technique exists to allow identification of individual particles on an air filter as cleavage fragments or fibers***

Currently no protocols (OSHA, NIOSH, MSHA, ASTM, ISO, AHERA) exist that provide guidance for the identification of cleavage fragments in samples. OSHA rules do not allow for the counting of cleavage fragments, but the identification of such fragments is subjective and left to the individual microscopist. One proposed method of determining if fibers in a bulk sample contain fibers that arose from cleavage processes is to measure a population of fibers and compute their average aspect ratio (ratio of length to width) [3]. This method is not widely accepted but requires that the population of fibers originate in the same material and that average aspect ratios be less than 20:1 to conclude that the fibers are cleavage fragments. The R.J. Lee Group suggests that by combining the air samples in El Dorado Hills a similar type of bulk analysis and conclusion can be made. But by doing so they have combined samples from several distinct locations that may have had dissimilar fiber size distributions and claimed that the average of all locations applies to each individual location. It is not appropriate to apply this technique to individual particles from air sampling filters [4]. Pooling individual fiber results from a number of different air sampling events is both statistically and methodologically invalid. Trying to analyze individual fibers as cleavage fragments is also invalid. At the individual particle level, precise morphological distinctions become unclear [5].

The R.J. Lee Group also argues that amphibole minerals containing high aluminum content should not be counted as asbestiform fibers. The report states that because the average aluminum level is too high, the particles cannot form an asbestiform habit (shape and size). It is not appropriate to make generalizations about individual fibers based on mean properties. In addition, the results indicate that particles meeting the dimensional criteria of fibers were

formed, regardless of the aluminum content. Toxicologically, precise mineralogical classification is unimportant, as will be discussed below. Many durable minerals not regulated as asbestos have been associated with disease [6].

The National Institute of Occupational Safety and Health (NIOSH) recommends that any particle meeting dimensional criteria for fibers (including particles cleaved from a nonasbestiform analog of asbestos mineral types) be counted as a fiber for risk assessment and regulatory purposes [4]. The dimensional definition of fibers specified by the Occupational Safety and Health Administration (OSHA) for regulatory purposes is particles observed under phase contrast microscopy having lengths 5 μm or longer and aspect ratios of 3:1 or greater [7]. The International Standards Organization (ISO) 10312 transmission electron microscopy method detects finer particles and captures much more detailed dimensional data on fibers, making it more flexible for use in today's developing risk assessment models [8]. The ISO method is written to count particles 0.5 μm or longer with aspect ratios of 5:1 or greater; however, the method is often modified to include particles with aspect ratios 3:1 or greater, which would be counted under phase contrast microscopy (PCM).

***Analogies to similar fibers***

The most convincing evidence that cleavage fragments should be counted as asbestiform fibers is their similarity to fibers known to cause disease. Cleavage fragments have the identical chemical structure as crystalline fibers from the same mineral. Populations of cleavage fragments and crystalline fibers may have different average aspect ratios, but individual cleavage fragments and fibers can be identical. Since two major characteristics contributing to fiber toxicity are length and width, one would predict fibers and cleavage fragments of similar length and width to have similar toxicities. This is supported by studies showing that other minerals or synthetic vitreous fibers of similar length and width cause lung diseases. Synthetic vitreous fibers have been implicated in mesothelioma induction and increased lung carcinomas and adenomas. Cullen *et al.* showed a combined carcinoma and adenoma increase in rats exposed to E-glass fibers [9]. McConnell demonstrated increased pleural mesothelioma in hamsters exposed to refractory ceramic fibers (RFC) [10]. RFC increases lung adenomas and carcinomas [11]. Environmental inhalation exposure to erionite (a fibrous zeolite material), is well known to produce mesothelioma [12–15]. The fibrous amphibole ferro-edenite has been shown epidemiologically and experimentally to induce mesothelioma [16,17]. Exposure to a material predominantly composed of winchite and richterite led to well documented adverse human health effects [6,18].

ATSDR recognizes that durability is another important fiber characteristic in assessing toxicity. Increased durability is associated with increased toxicity. For example, the fibrous silicate, balangeroite, showed greater durability and *in vitro* toxicity than the amphibole asbestos, crocidolite [19]. Durability may be influenced by surface chemistry, leading to possible differences in durability of crystalline fibers and cleavage fragments. However, research on the differences in durability of various asbestos minerals and cleavage fragments is insufficient.

*.Epidemiological studies suggest that cleavage fragments contribute to disease*

Several human epidemiological studies have demonstrated a relationship between asbestos-related diseases, including pleural disease and mesothelioma, and exposure to a variety of fibers of various mineral types. Elevated levels of human disease have been documented from environmental exposures in many locations worldwide, including Turkey, Corsica, New Caledonia, and China [20–26]. Environmental exposures and disease have been documented in mining communities in Montana and in South Africa, Canada, and Australia where certain asbestiform and other minerals were processed [18,27–29]. Recent epidemiological evidence suggests an association between residential proximity to naturally occurring asbestos deposits in California and mesothelioma risk [30].

In many of these studies, characterization of exposures was very limited. However, the nature of the materials and processes suggests a wide variety of fiber lengths and morphology. Some human epidemiologic studies and case reports have suggested the occurrence of disease in association with exposures to airborne particles with lower aspect ratios [26,31,32]. In Libby, Montana, where adverse health effects have been well documented, fiber characterization revealed that a large percentage of fibers did not meet the criteria suggested in the R.J. Lee Group report [6].

*Adequate animal and human studies of cleavage fragments are needed*

The similarity of cleavage fragments to other fibrous structures that cause disease and the suggestive evidence from epidemiology studies that cleavage fragments are involved in disease is sufficient to consider them toxic. To confirm this analysis toxicity studies on cleavage fragments are needed. Unfortunately, adequate toxicity studies are not available.

The ideal studies would compare the toxicity of animals exposed to cleavage fragments and asbestiform fibers of the same concentration and fiber size distributions, with appropriate controls. Unfortunately, such studies have not been performed because of the difficulties in obtaining suitable materials.

Some toxicity studies have assessed the role of cleavage fragments by using materials that were either predominately cleavage fragments or asbestiform fibers. However, these studies are of limited use because of confounding factors. For example, a toxicity study in animals was performed by Davis *et al* [33]. The researchers injected six different test materials of asbestos fibers and cleavage fragments into the peritonea of rats. Three of the materials were mostly tremolite asbestiform fibers and the other three materials were mostly cleavage fragments. The three asbestiform materials showed a 97%–100% incidence of mesothelioma. The three cleavage fragment materials showed a 6%–67% incidence of mesothelioma. The study is complicated by the fact that the cleavage fragment materials showing the highest mesothelioma incidence contained long thin structures which were not clearly identified as being either asbestiform fibers or cleavage fragments. If they were asbestiform fibers, the incidence rate could be an overestimate. The cleavage fragment material showing the lowest mesothelioma incidence (6%) was consisted almost entirely of short blocky cleavage fragments. That could show that cleavage fragment length is important and that even short cleavage fragments induce tumors. Some

investigators have argued that a 6% incidence of mesothelioma in rats is not above the incidence associated with background levels [34].

*Summary*

The central issues in the debate over cleavage fragments lie not only in the practical issues of whether they can be consistently detected, but in whether the toxicity of cleavage fragments differs from asbestiform fibers.

Cleavage fragments are identical in chemical structure to their corresponding mineral asbestiform fibers and can be identical in size to fibers that are known carcinogens. Until a scientific consensus is reached on the correct methodology to detect and differentiate cleavage fragments from asbestiform fibers in a sample and adequate toxicological studies on potency are performed, ATSDR will continue to treat cleavage fragments as asbestiform fibers when they have an aspect ratio of 3:1 or greater.

**Other considerations**

Other governmental agencies and expert panels convened by governmental and medical organizations have reached similar conclusions as ATSDR regarding cleavage fragments:

**NIOSH** – "In 1990 testimony before OSHA, NIOSH broadened its science-based definition of "asbestos" as a result of concerns about the microscopic identification of the six regulated asbestos minerals.... NIOSH bases this expanded "asbestos" definition – encompassing the entire solid-solution mineral series for each of the six currently regulated asbestos minerals and including cleavage fragments from the non-fibrous forms of these minerals – on scientific evidence from cellular and animal studies suggesting that dimension, specifically length and diameter, as well as durability, may be more critical factors in causing disease than chemical or elemental composition." [35]

**EPA Peer Consultation** – "The previous concerns notwithstanding, several panelists commented on the role of cleavage fragments in the proposed risk assessment methodology. One panelist, for example, indicated that there is no reason to believe that cleavage fragments would behave any differently in the human lung than asbestiform fibers of the same dimensions and durability; he added that this conclusion was also reached by the American Thoracic Society Committee in 1990 (Weill et al. 1990). This panelist acknowledged, however, that expert mineralogists have differing opinions on the role of cleavage fragments. Several other panelists agreed that it is reasonable to assume that cleavage fragments and asbestos fibers of the same dimension and durability would elicit similar toxic responses." [36].

**American Thoracic Society** – "Because of the lack of consensus among mineralogists, as well as the limited information about the minerals present in most published human and animal data (i.e., whether the particles used or observed really are fibers or cleavage fragments), we have to a great extent ignored the distinction and ended up treating most of the data as based on "fibers" of various sizes. The committee recognizes that this is not an ideal solution, and where stronger

evidence of the cleavage fragment or asbestiform nature of a particular fiber exists, we have noted it. However, until there is reasonable mineralogic unanimity both on general definition and the classification of specific samples, and the animal experimentation with such classified materials, it appears to us impossible to draw general conclusion about biologic effects based on the distinction between cleavage fragments and asbestiform fibers." [37]

**Conclusions**

- No acceptable or accredited methods exist to distinguish between the continuum of particles and fibers found in mineralogical samples (e.g., distinguish commercial grades of asbestos, other asbestiform fibers, or cleavage fragments).
- Epidemiology literature shows clear evidence that asbestiform fibers cause disease and suggests that exposures are to a mixture of fibers including cleavage fragments. Some of these mixtures have low aspect ratios but lead to disease.
- The similarity of cleavage fragments to other fibrous structures that cause disease is sufficient to consider them similar in action to asbestiform fibers.
- Toxicity data are insufficient to conclude a difference in potency of cleavage fragments from asbestiform fibers of similar mineralogy.

These conclusions are supported by current asbestos science. Similar conclusions have been reached by a number of governmental, medical, and scientific researchers and organizations. ATSDR recognizes that these issues reflect an evolving science and will modify these conclusions if warranted by additional research in the future.

**Recommendations**

1. ATSDR recommends adherence to the currently accepted counting methods, except when deviations can be well justified (*e.g.*, extracting PCM equivalents from ISO data). Mineralogy and fiber size should be considered when performing health-based assessments.

2. ATSDR recommends minimizing exposures to particles that are counted as asbestos, in accordance with recognized asbestos analytical procedures, in environments that could contain asbestos.

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Region 9 folks,

I would like you to take a look at this to see if it will be causing any policy headaches or problems with the manner in which you will be counting "fibers" at El Dorado.

Currently this document is out for peer review and will be ATSDR's position on how we will deal with cleavage fragments at sites across the country, until such time as new scientific knowledge becomes available. Essentially we will include cleavage fragments when counting because of their known structural similarity to known carcinogens and the lack of any consensus or good study demonstrating their lack of toxicity. The inability to analytically detect cleavage fragments is an important practical issue but not the decisive factor. The proper public health strategy is to include them at this time. (Note: since we will be using only PCMe and/or protocol structures in our health evaluation I do not think cleavage fragments are going to represent a substantial portion of total fibers).

ATSDR has a mechanism for sharing this document with EPA headquarters. They will be receiving it after peer review but before any public release. We would like to use that mechanism so please do not share it with HQ. I realize this could put you into a bind with any type of formal response to us, so I would be quite satisfied to keep this very informal and just as a "heads up" kind of document.

I will gladly accept editorial and scientific comments. But I really want you to concentrate on policy and if you foresee any "monkey wrenches" this will throw into the El Dorado work.

Thanks
John

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